Supplementary File 1. Items from the World Health Organization Trial Registration Data Set.

DATA CATEGORY	INFORMATION
Primary registry and trial identifying number	ClinicalTrials.gov NCT02932358
Date of registration in primary registry	11 October 2016
Secondary identifying numbers	CAAE 57717516.3.1001.5330
Source of monetary or material support	The present study was funded by the Brazilian Ministry of Health through the Program of Institutional Development of the Brazilian Unified Health System (PROADI-SUS).
Primary sponsor	Brazilian Ministry of Health
Secondary sponsor	Brazilian Ministry of Health
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Public title	ICU VISITS STUDY
Scientific title	Effectiveness and safety of a flexible family visitation model in adult intensive care units: a cluster-randomized, crossover trial
Countries of recruitment	Brazil
Health conditions or problems studied	Delirium, ICU-acquired infections, anxiety, depression, burnout syndrome.

Interventions	1) Active comparator: Flexible family visitation model – ICU visitation during 12 consecutive hours per day. 2) Control comparator: Restrictive family visitation model – ICU visitation according to local policies.
Key inclusion and exclusion criteria	1) ICUs - Inclusion criteria: Mixed medical-surgical ICUs with at least 6 beds and a restrictive policy of family visitation (<4.5 h/day). - Exclusion criteria: ICUs with structural or organizational impediments to flexible family visitation. 2) Patients - Inclusion criteria: patients aged ≥18 years admitted to the ICU. - Exclusion criteria: coma lasting > 96hs, cerebral death, aphasia, severe hearing deficit, predicted ICU length of stay <48 h, exclusive palliative treatment at ICU admission, unavailability of a family member to participate in the flexible family visits, unlikelihood to survive >24 h, prisoner status, readmission to the ICU after enrolment in the study. 3) Family members - Inclusion criteria: closest family member of a ICU patient recruited in the study. - Exclusion criteria: family members who do not speak Portuguese or have serious impediment in answering the self-applied questionnaires

	4) ICU professionals - Inclusion criteria: ICU bedside professionals (physicians, nurses, nursing technicians, and physiotherapists) who assist patients during the daytime for at least 20 h per week. - Exclusion criteria: professionals who have a planned leave of absence of >15 days during the study.
Study type	Interventional Allocation: randomized Intervention model: crossover assignment Masking: open label Primary purpose: prevention
Date of first enrollment	28 April 2017
Target sample size	1650 patients
Recruitment status	Recruiting
Primary outcome	Cumulative incidence of delirium
Key secondary outcomes	Daily hazard of delirium, ventilator-free days, any ICU-acquired infections, ICU length of stay, and all-cause hospital mortality among the patients; symptoms of anxiety and depression and satisfaction among the family members; and prevalence of symptoms of burnout among the ICU professionals.